

Remarks

Claims 1-10, 12-18, 20-28 and 30-41 are pending in the present application. Claim 13 has been cancelled. The following rejections are at issue and are set forth by number in the order in which they are addressed:

1. Claim 13 stands rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite;
2. Claims 1-10, 12-18, 20-28, and 30-41 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly being nonenabled;
3. Claim 1-10, 12-18, 20-28, and 30-41 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing new matter.

Claims 1, 21, and 41 have been amended and Claims 29 and 42 have been canceled in order to further Applicant's business interests and the prosecution of the present application in a manner consistent with the PTO's Patent Business Goals (PBG; 65 Fed. Reg. 54603 (September 8, 2000)), and not in acquiescence to the Examiner's arguments and while reserving the right to prosecute the original (or similar) claims in the future. None of the claim amendments made herein are intended to narrow the scope of any of the amended claims within the meaning of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 56 USPQ2d 1865 (Fed. Cir. 2000) or related cases.

1. The Claims are Definite

Claim 13 has been cancelled, thus the rejection is moot.

2. The Claims are Enabled

Claims 1-10, 12-18, and 20-41 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly being nonenabled. Applicants respectfully disagree.

The rejection is traversed because the Examiner has failed to establish a *prima facie* case of non-enablement. The standard to be applied in assessing enablement is whether the experimentation needed to practice the claimed invention is undue or unreasonable. *See*

TRAINING MATERIALS FOR EXAMINING PATENT APPLICATIONS WITH RESPECT TO 35 U.S.C. SECTION 112, FIRST PARAGRAPH-ENABLEMENT CHEMICAL/BIOTECHNICAL APPLICATIONS, *citing In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). When applying this standard, the burden is on the Examiner to make a *prima facie* case of non-enablement that is well grounded in scientific reasoning or evidence. *See In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993); *See also* MPEP §706.03 and §2164.04. This is because without a reason to doubt the truth of the statements made in the patent application, the application must be considered enabling (*Wright*, 27 USPQ2d at 1513).

The specification provides extensive examples demonstrating methods for transducing host cells. *See, e.g.*, examples 2-19, 26-28. The specification also describes in detail how to use these methods to serially transduce cells. *See, e.g.*, Specification at 47:4-48:10. The Specification also provides that the host cell produced by this method can have from 10 to more than 100 copies of a retrovirus integrated into its genome. (“In some embodiments, the genome comprises at least 5, and preferably, at least 100 integrated integrating vectors.” Specification 3:25-26).

Based on the teaching of the specification, obtaining the claimed number of integration is within the skill in the art. The Examiner’s attention is respectfully directed to the Declaration of Dr. Gregory Bleck, which accompanies this response. In the Declaration, Dr. Bleck states that the methods described in the specification can be used to produce cell lines containing more than 200 retroviral integrations. Dr. Bleck then provides data from a representative example where 113 integrations were obtained using the methods described in the specification. As can be seen, contrary to the Examiner’s arguments in paragraph 12 of the specification, an “untold number of cells” did not need to be screened to identify clonal cell lines with greater than 50 integrants. Accordingly, the specification enables the production of the claimed cell lines and methods of producing such cell lines.

3. The Claims do not Contain New Matter

Claim 1-10, 12-18, 20-28, and 30-41 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing new matter. The Examiner argues that’s “simply because 20 falls within the ranges disclosed provides no evidence that the endpoints of the range at 20 was

ever contemplated at the time of the invention.” Applicants respectfully disagree. The specification clearly establishes that the Applicants contemplates any number of integrations within the range. As provided in the Specification, page 3:25-26: “In some embodiments, the genome comprises at least 5, and preferably, at least 100 integrated integrating vectors.” As can be seen, the claimed range of 20 to 100 integrated vectors is clearly within the described range of 5 to 100 integrated vectors per cells.

Applicants further note that the subject matter of claim need not be described literally or “in *ipsis verbis*” in order for the specification to satisfy the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 969, 169 USPQ 795, 796 (C.C.P.A. 1971). It is clear that the claimed lower limit of 20 integrations per cell is within the ranges taught in the specification. Thus, support for the claim limitations exists and the claims limitations are new matter. In this regard, the limitations are similar to those addressed by the CCPA in *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). There, the specification described a step of a process as achieving a solids concentration of a coffee extract of 25-60% and gave specific examples of 36% and 50%. The claims at issue specified a solids concentration of between 35% and 60%. The CCPA overturned the rejection of this claim, finding that the narrowed range was within the range taught in the patent specification. *Id.* at 264, 191 USPQ at 98. In the instant case, the range of 20-100 integrations per cell is clearly within the ranges taught in the specification. There is no new matter.

As such, the claim limitation of 20 to 100 integrated vectors per cell is supported by the specification. Applicants respectfully request that this ground of rejection be withdrawn.

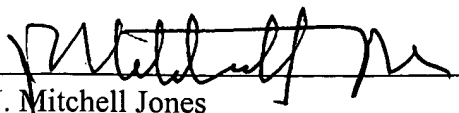
CONCLUSION

All grounds of rejection and objection of the Office Action of May 2, 2006 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

PATENT

Attorney Docket No. **GALA-08484**

Dated: August 2, 2006



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